UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

EGM 02-003

November 12, 2002

MEMORANDUM TO: Hubert J. Miller, Regional Administrator, Region I
Luis A. Reyes, Regional Administrator, Region II
James Dyer, Regional Administrator, Region III
Ellis W. Merschoff, Regional Administrator, Region IV
R. William Borchardt, Associate Director for Inspection and Programs, NRR
Brian W. Sheron, Associate Director for Project Licensing and Technical Analysis, NRR
Robert Pierson, Director, Division of Fuel Cycle Safety and Safeguards, NMSS
Donald A. Cool, Director, Division of Industrial and Medical Nuclear Safety, NMSS
John T. Greeves, Director, Division of Waste Management, NMSS
E. William Brach, Director, Spent Fuel Project Office, NMSS

FROM: Frank J. Congel, Director **/RA/**
Office of Enforcement

SUBJECT: ENFORCEMENT GUIDANCE MEMORANDUM - ENFORCEMENT OF 10 CFR 35.2432 -RECORDS OF CALIBRATION MEASUREMENTS OF BRACHYTHERAPY SOURCES

The purpose of this memorandum is to provide enforcement guidance that the NRC will follow to exercise enforcement discretion for certain violations of requirements in 10 CFR 35.2432(b)(5), "Records of calibration measurements of brachytherapy sources."

On April 24, 2002, the NRC published a Final Rule (67 FR 20250) amending its regulations regarding the medical use of byproduct material that became effective on October 24, 2002. On November 7, 2002, the NRC issued Regulatory Issue Summary (RIS) 2002-20, "Clarification of Requirements Under 10 CFR 35.432, "Calibration Measurements of Brachytherapy Sources," (attached). The RIS provides the information that although §35.2432(b)(5) states that "the signature of the authorized medical physicist" is part of the required record for manual brachytherapy source calibrations, there is no corresponding requirement in 10 CFR 35.432 to have those calibrations performed by an authorized medical physicist (AMP).

This enforcement discretion should be exercised for violations of 10 CFR 35.2432(b)(2) involving records of calibration measurements of manual brachytherapy sources that do not contain an AMP's signature. This policy will remain in effect while NRC evaluates a revision to the record keeping requirements for the AMP's signature.

The staff should follow the guidance in Section 6.3.6 of the Enforcement Manual for exercising enforcement discretion in accordance with Section VII.B.6 of the Enforcement Policy (e.g., obtaining an EA number, appropriate coordination, etc.).

The following language should be included in the text of the report discussing the inspection finding when exercising enforcement discretion in accordance with this EGM:

> A violation of 10 CFR 35.2432(b)(5) was identified for failure to include the signature of the authorized medical physicist on records of calibration measurements of brachytherapy sources. Since the NRC has identified an inconsistency between 10 CFR 35.432, Calibration measurements of brachytherapy sources, and its record-keeping requirement described in 10 CFR 35.2432(b)(5), involving the requirement for an authorized medical physicist's signature, the NRC is exercising enforcement discretion in accordance with Section VII.B.6 of the NRC Enforcement Policy, and not issuing any enforcement action for this violation.

Attachment:

NRC's Regulatory Issue Summary 2002-20 , "Clarification of Requirements Under 10 CFR 35.432, "Calibration Measurements of Brachytherapy Sources"

cc:
W. Kane, DEDR
C. Paperiello, DEDMRS
L. Chandler, OGC
M. Virgilio, NMSS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555-0001

November 7, 2002

# NRC REGULATORY ISSUE SUMMARY 2002-20 CLARIFICATION OF REQUIREMENTS UNDER 10 CFR 35.432, "CALIBRATION MEASUREMENTS OF BRACHYTHERAPY SOURCES"

ADDRESSEES:

All medical licensees.

INTENT:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to provide clarification to addressees concerning the requirements under 10 CFR 35.432, "Calibration of measurements of brachytherapy sources." No specific action or written response is required.

BACKGROUND:

The requirements governing calibration of manual brachytherapy sources are contained in 10 CFR 35.432, and the associated record-keeping requirements are contained in 10 CFR 35.2432. It has recently been identified that 10 CFR 35.2432(b)(5) states that "The signature of the authorized medical physicist" is part of the required record for 10 CFR 35.432 calibrations. However, there is no corresponding requirement, in 10 CFR 35.432, to have an authorized medical physicist (AMP) perform calibrations of manual brachytherapy sources.

The requirement for an AMP's signature was intended to be associated with 10 CFR 35.2433, "Records of decay of strontium-90 sources for ophthalmic treatments." An AMP is required, under 10 CFR 35.433 (the requirement associated with 10 CFR 35.2433), to calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments.

SUMMARY OF ISSUE:

An AMP is not required to perform the calibration of manual brachytherapy sources. NRC plans to exercise enforcement discretion in not citing licensees whose records of calibration measurements of manual brachytherapy sources do not contain an AMP's signature. This policy will remain in effect while NRC evaluates a revision to the record-keeping requirements in 10 CFR 35.2432 and 35.2433.

**ML023100622**

This RIS requires no specific action nor written response. If you have any questions about this summary, please contact the technical contact listed below or the appropriate regional office.

Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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Attachment:
- List of recently issued NRC Regulatory Issue Summaries

# LIST OF RECENTLY ISSUED NRC REGULATORY ISSUE SUMMARIES

| Regulatory Issue Summary No. | Subject | Date of Issuance | Issued to |
|---|---|---|---|
| 2002-19 | New Modalities to be Regulated Under 10 CFR 35.1000 | 10/21/2002 | All medical licensees authorized to use byproduct material for therapeutic administration. |
| 2002-18 | Issuance of Orders Imposing Additional Physical Protection Measures for the Transportation of Spent Nuclear Fuel Greater than 100 Grams | 10/03/2002 | All U.S. Nuclear Regulatory Commission specific power reactor licensees, research and test reactor licensees, independent spent fuel storage installation licensees, and special nuclear material licensees, who possess spent nuclear fuel; and general licensees under 10 CFR 70.20a who transport spent nuclear fuel greater than 100 grams. |
| 2002-14, Sup. 1 | Proposed Changes to the Safety System Unavailability Performance Indicators | 09/30/2002 | All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel. |
| 2002-17 | Guidance on Performing Military Service Verification | 09/19/2002 | All holders of operating licenses for nuclear power reactors. |
| 2002-16 | Current Incident Response Issues | 09/13/2002 | All holders of operating licenses for nuclear power plants. |
| 2002-15 | NRC Approval of Commercial Data Encryption Systems for the Electronic Transmission of Safeguards Information | 08/28/2002 | All authorized recipients and holders of sensitive unclassified safeguards information (SGI). |

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